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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|-----------------------|---------------------|------------------|
| 10/802,166      | 03/17/2004  | James Robert Schwartz | 9184M               | 4150             |

27752 7590 12/07/2011  
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| EXAMINER |
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ARNOLD, ERNST V

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1613

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| MAIL DATE | DELIVERY MODE |
|-----------|---------------|

12/07/2011

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/802,166 | <b>Applicant(s)</b><br>SCHWARTZ ET AL. |  |
|                              | <b>Examiner</b><br>ERNST ARNOLD      | <b>Art Unit</b><br>1613                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2011.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 5) ☒ Claim(s) 1,3,7-13,18-25 and 27 is/are pending in the application.
- 5a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) 1, 3, 7-13, 18-25 and 27 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                          |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/22/11 has been entered.

Claims 2, 4-6, 14-17 and 26 have been cancelled. Claims 1, 3, 7-13, 18-25 and 27 are pending and under examination.

#### **Withdrawn rejections:**

Applicant's amendments, Declaration and arguments filed 6/22/11 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn.

The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make

Art Unit: 1613

and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 7-13, 18-25 and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The factors considered in the Written Description requirement are (1) *level of skill and knowledge in the art*, (2) *partial structure*, (3) *physical and/or chemical properties*, (4) *functional characteristics alone or coupled with a known or disclosed correlation between structure and function*, and the (5) *method of making the claimed invention*.

While all of the factors have been considered, only those required for a *prima facie* case are set forth below.

The specification merely discloses, without more, that "other impurities may be incorporated into the crystal lattice" [0036]. The identity and amount of impurities is unknown.

The claims are drawn to a composition comprising an impurity containing basic zinc carbonate.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the written description inquiry, is whatever is now claimed (see page 1117).

The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. The present claim

encompasses any and all impurities that can exist. There is substantial variability among the species of impurities encompassed within the scope of the claims because not a single impurity is identified by Applicant that provides the desired function. Applicant has not described what the impurity is. Just claiming "an impurity" will not substitute for written description of the structure of the impurity. The invention should be explained in such a way as to describe what the invention is. "An impurity" fails to distinguish the impurity from other molecules or agents that can perform the same functions.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Consequently, the Examiner notes that the claimed invention which is drawn to a genus of impurities may be adequately described if there is a (1) sufficient description of a representative number of species, or (2) by disclosure of relevant, identifying characteristics sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. Here, the specification does not disclose a single common structural feature shared by the members of the claimed genus, i.e., impurities. Therefore, the disclosure of impurities does not provide an adequate description of the claimed genus of impurities.

Weighing all the factors, the breadth of the claims reading on any and all impurities, the lack of correlation between structure and function of the impurities, level of knowledge and skill in the art, one of ordinary skill in the art would not recognize from the disclosure that the

Art Unit: 1613

applicant was in possession of the genus of impurities which comprise an impurity containing basic zinc carbonate. At best, it simply indicates that one should run tests on a wide spectrum of compounds in the hope that at least one of them will work. Neither the exemplary embodiments nor the specification's general method appears to describe structural features, in structural terms, that are common to the genus. That is, the specification provides neither a representative number of impurities to describe the claimed genus, nor does it provide a description of structural features that are common to the impurities. In essence, the specification simply directs those skilled in the art to go figure out for themselves the structure of the claimed impurity.

The written description requirement is not satisfied.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 7-13, 18-25 and 27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for basic zinc carbonate, does not reasonably provide enablement for an impurity containing basic zinc carbonate. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims without an undue amount of experimentation.

**Let the Examiner be clear: Applicant is not enabled for an impurity containing basic zinc carbonate.**

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: 1) scope or breadth of the claims; 2) nature of the invention; 3) relative level of skill possessed by one of ordinary skill in the art; 4) state of, or the amount of knowledge in, the prior art; 5) level or degree of predictability, or a lack thereof, in the art; 6) amount of guidance or direction provided by the inventor; 7) presence or absence of working examples; and 8) quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure. When the above factors are weighed, it is the Examiner's position that one skilled in the art could not practice the invention without undue experimentation. While all of the factors have been considered, only those required for a *prima facie* case are set forth below.

1) Scope or breadth of the claims

The claims are broader in scope than the enabling disclosure. The specification merely discloses, without more, that "other impurities may be incorporated into the crystal lattice" [0036]. However, Applicant is claiming an unknown impurity containing basic zinc carbonate.

2) Nature of the invention

The nature of the invention is directed to compositions of zinc layered materials.

3) Relative level of skill possessed by one of ordinary skill in the art

MPEP 2141.03 states (in part), "A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton." *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 167 LEd2d 705, 82 USPQ2d 1385, 1397 (2007). "[I]n many cases a person of ordinary skill will

Art Unit: 1613

be able to fit the teachings of multiple patents together like pieces of a puzzle.” Id. Office personnel may also take into account “the inferences and creative steps that a person of ordinary skill in the art would employ.” Id. At 1396, 82 USPQ2d at 1396. The “hypothetical person having ordinary skill in the art’ to which the claimed subject matter pertains would, of necessity have the capability of understanding the scientific and engineering principles applicable to the pertinent art.” Ex parte Hiyamizu, 10 USPQ2d 1393, 1394 (Bd. Pat. App. & Inter. 1988) (The Board disagreed with the examiner’s definition of one of ordinary skill in the art (a doctorate level engineer or scientist working at least 40 hours per week in semiconductor research or development), finding that the hypothetical person is not definable by way of credentials, and that the evidence in the application did not support the conclusion that such a person would require a doctorate or equivalent knowledge in science or engineering.).

4) State of, or the amount of knowledge in, the prior art

Bhat et al. (WO 96/25913) teach personal care product compositions comprising a surfactant and the zinc salt monophasic zinc hydroxycarbonate in an amount of 0.1-20 % by weight (Claims 1 and 2).

“Trace amounts of an impurity do not affect the basic chemical composition or the chemical formula of a mineral, and thus do not affect its classification as a species.” (page 3 of 4: Section 2: Physical Characteristics of Minerals [online] downloaded from: [http://dave.ucsc.edu/myrtreia/physical\\_character.html](http://dave.ucsc.edu/myrtreia/physical_character.html) on 11/30/11; published 12/08/2002; 4 pages.)

5) Level or degree of predictability, or a lack thereof, in the art

6) Amount of guidance or direction provided by the inventor



Applicant was required to provide in the specification additional guidance and direction with respect to how use the claimed subject matter in order for the application to be enabled with respect to the full scope of the claimed invention. Although the instant specification discloses that “other impurities may be incorporated into the crystal lattice” [0036], it remains silent on the identity of the impurity.

7) Presence or absence of working examples

The specification fails to provide scientific data and working embodiments with respect to the analysis and characterization of the impurity.

8) Quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure

**From MPEP 2164” The Enablement Requirement [R-2]**

“The enablement requirement refers to the requirement of 35 U.S.C. 112, first paragraph that the specification describe how to make and how to use the invention. The invention that one skilled in the art must be enabled to make and use is that defined by the claim(s) of the particular application or patent. The purpose of the requirement that the specification describe the invention in such terms that one skilled in the art can make and use the claimed invention is to ensure that the invention is communicated to the interested public in a meaningful way. The information contained in the disclosure of an application must be sufficient to inform those skilled in the relevant art how to both make and use the claimed invention.”

One of ordinary skill in the art would have to conduct a myriad number of experiments comprising guessing in the dark as to what the impurity might be and how much is present. This is very problematic when the ordinary artisan understands that trace amounts of an impurity do

Art Unit: 1613

not affect the basic chemical composition or the chemical formula of a mineral and therefore how much impurity of what type is required to provide the desired function and then at what point is the ‘impurity’ no longer an impurity but a functional component of the composition. As a result, one of ordinary skill in the art would be required to conduct an undue amount of experimentation to try and figure out what the impurity might be and in what amount that produces the desired function. In other words, the ordinary artisan cannot make or use this invention without knowledge of what the impurity might be because Applicant has not identified the impurity upon which Applicant bases their invention.

Genetech, 108 F.3d at 1366 states that “a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion” and “patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable.” (*Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997)).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Art Unit: 1613

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Please note that with regard to the scope of enablement rejection above, this rejection is over “basic zinc carbonate” which is subject matter that is enabled by Applicant.

Claims 1, 3, 7-13, 18-25 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gavin et al. (WO 01/00151) and Bhat et al. (WO 96/25913).

Applicant claims:

- 1) (previously presented) A composition comprising:
  - a) from 0.001% to 5 % of a zinc-containing layered material wherein the zinc-containing layered material is an impurity containing basic zinc carbonate;
  - b) from 10 % to 50% of a surfactant including a surfactant with an anionic functional group;
  - c) from 0.01% to 5% of a pyrithione or a polyvalent metal salt of a pyrithione;wherein the impurity containing basic zinc carbonate has a relative zinc lability of greater than 15% and further wherein the ratio of surfactant to impurity containing basic zinc carbonate is greater than or equal to 2 to 1.

**Determination of the scope and content of the prior art**

**(MPEP 2141.01)**

Gavin et al. teach a topical anti-dandruff composition for treating microbes comprising:

- From 0.001% to 10% zinc pyrithione or polyvalent metal salts of pyrithione;
- from 0.001 to about 10% of a metal ion source such as zinc salt or copper salt or mixtures thereof; and
- an anionic detergents surfactant (about 5 to about 50% by weight) for a topical carrier (Page 8, lines 10-15 and Claim 1).

Less than 50% of the polyvalent metal salt dissociates into free pyrithione in the composition (claim 2). The ratio of surfactant to zinc containing layered material can be greater than or equal to 2 to 1 by simple manipulation of the amounts taught above. The pH of the compositions ranges from about 2 to about 10 and most preferably from about 5.5 to about 7.5 thus within the scope of instant claims 9-11 (Page 7, lines 7-9). The addition of cationic deposition polymers (instant claim 18) is taught (Page 20, lines 30-34-page 25, line 30). The addition of conditioning agents (instant claim 19) is taught (Page 35, line 12- page 47, line 16). Suspending or thickening agents are anticipated and crystalline suspending agents are preferred thus reading on instant claims 20-22 (Page 18, line 27-page 20, line 28) Methods pertaining to treating microbial infections preferably related to dandruff and treating athlete's foot, a contagious fungal infection, are provided hence reading on the method of instant claims 23-25 (Claim 9). Gavin et al. teaches applying the composition and then rinsing off with water (page 50, lines 12-17).

Bhat et al. teach personal care product compositions comprising a surfactant and the zinc salt monophasic zinc hydroxycarbonate in an amount of 0.1-20 % by weight (Claims 1 and 2).

Art Unit: 1613

The structure of the zinc compound is  $\text{Zn}_5(\text{OH})_6(\text{CO}_3)_2 \cdot X \text{H}_2\text{O}$  where X varies between 0 and 4 (Page 6, lines 23-27). When  $X=0$  then the same formula for basic zinc carbonate as disclosed by Applicant is taught (see instant specification page 6, line 6). It is the Examiner's position that the basic zinc carbonate taught by Bhat et al. would have the same level of zinc lability as instantly claimed (claims 1, 12 and 13) in the absence of evidence to the contrary. Indeed, Bhat et al. teach release of zinc ions from zinc hydroxycarbonate (page 7, lines 31-35). **Bhat et al. teach synergistic action of zinc hydroxycarbonate with antidandruff actives like zinc pyrithione in shampoos** (page 8, lines 1-4). Bhat et al. teach the surfactant can be sodium lauryl sulphate, an anionic surfactant, in the amount of 2.5% (Page 12, line 10).

### **Ascertainment of the difference between the prior art and the claims**

#### **(MPEP 2141.02)**

1. Gavin et al. do not expressly teach a composition comprising as the zinc containing layered material is an impurity containing basic zinc carbonate that has a zinc lability of greater than 15%, 20% or 25%. This deficiency in Gavin et al. is cured by the teachings of Bhat et al.

2. Gavin et al. do not expressly teach a method comprising wetting the hair or skin first with water and then applying the composition.

### **Finding of prima facie obviousness**

#### **Rational and Motivation (MPEP 2142-2143)**

Art Unit: 1613

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make the composition of Gavin et al. comprising as the zinc containing layered material an impurity containing basic zinc carbonate that has a zinc lability of greater than 15%, 20% or 25%, as suggested by Bhat et al., to the composition of Gavin et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Gavin et al. suggest adding zinc salts to the composition but not specifically basic zinc carbonate and Bhat et al. cure this deficiency by teaching the *synergistic action of zinc hydroxycarbonate with antidandruff actives like zinc pyrithione in shampoos*. One of ordinary skill in the art would desire the synergistic action of the zinc hydroxycarbonate with the anti-dandruff active zinc pyrithione in the composition to produce the best results. The “impurity containing basic zinc carbonate” is intrinsic in the composition of Bhat et al. because all that is required that some element/component of infinitesimally small amount be present since the instant claims do not define the 'impurity' or the amount of the 'impurity' present. Hence, a single atom would represent an 'impurity' but not be within means of detection. The 'zinc lability' is an intrinsic property of the zinc salts since they are the same as instantly claimed. With regards to the other zinc and copper salts, it is merely judicious selection of zinc and copper salts by one of ordinary skill in the art in the absence of evidence to the contrary. One of ordinary skill in the art would have had a reasonable expectation of success because it appears that any zinc or copper or mixed zinc-copper salt will work in this invention.

2. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to perform the method of Gavin et al. by wetting the hair or skin first and then applying the composition and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because it reads on stepping into a shower with the water running and getting wet, applying the composition and then rinsing it off. It is well within the skill of the ordinary artisan to take a shower and not inventive skill is required to get wet first before applying the composition in the absence of evidence to the contrary.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

**Response to arguments:**

Applicant has provided a Declaration under 37 CFR 1.132 for the Examiner's consideration. In this Declaration, the relative zinc lability of 3 samples, Bruggemann, Elementis and Cater, were presented and Applicant argued that the unknown impurity containing

Art Unit: 1613

Bruggemann sample has a higher zinc lability which translates into a higher efficacy in reduction of malassezia count (See Table 1 and Graph 1 of the Declaration) and this is an important attribute of the claimed invention to achieve high performance (remarks page 8 of 13).

Respectfully, this Declaration is not persuasive. For starters, this is not a side by side comparison with the closest prior art and there is no standard deviation for Table 1 and therefore the statistical significance is unknown. From MPEP **716.02(b): Burden on Applicant [R-2]**

**I. < BURDEN ON APPLICANT TO ESTABLISH RESULTS ARE UNEXPECTED AND SIGNIFICANT**

The evidence relied \*>upon< should establish "that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance." *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992).

**From MPEP 716.02(e) Comparison With Closest Prior Art [R-2]**

An affidavit or declaration under 37 CFR 1.132 must compare the claimed subject matter with the closest prior art to be effective to rebut a *prima facie* case of obviousness. *In re Burckel*, 592 F.2d 1175, 201 USPQ 67 (CCPA 1979).

Secondly, careful analytical characterization of the samples was not performed. Applicant relies on some ethereal ‘impurity’ that provides the basis for the results. Applicant truly has no idea what the ‘impurity’ might be and what would happen if Bruggemann altered their manufacturing process to remove impurities then how would anyone make or use this invention? It is simply not sufficient to assert the impurities are an important part of the attributes of the invention and then not identify what that might be. Consequently, the ordinary artisan cannot make or use the invention without knowledge of what the impurity is as discussed supra.



Thirdly, the ordinary artisan has a finite selection of commercial sources of basic zinc carbonate and, as shown by Applicant, Bruggemann, Elementis and Cater are examples, and Applicant's own work has shown that all have a relative zinc lability of greater than the instantly claimed amounts. Consequently, it appears that selection of any commercial source of basic zinc carbonate provides a relative zinc lability that reads on the instant claims.

Applicant argues that the monophasic basic zinc carbonate of Bhat et al. is without any other impurity phases. This argument is not persuasive because the absence of an impurity phase does not necessarily mean that an impurity itself is not present. If the impurity phase can be measured then it is logical to reason that enough impurity is present to be detected by that method. However, if an impurity phase is not present that does not unequivocally mean that an impurity itself is not present because the impurity can be present at an amount below the method detection limits and another method, such as elemental analysis which is routinely performed by analytical chemists, is required to ascertain if the sample is indeed pure or not. Furthermore, the composition of Bhat et al. is open to the inclusion of other elements including non-monophasic zinc hydroxycarbonate which is taught by Bhat et al. to be precipitated at room temperature (page 7, lines 16-17).

Respectfully, these arguments are not persuasive and the claims remain rejected.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined

Art Unit: 1613

application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**Response to arguments:**

1. Claims 1, 3, 7-13, 18-22 and 25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 8-12, 16-32, and 34-39 of copending Application No. 11/602770. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant subject matter embraces or are embraced by the subject matter of the copending application. The copending application discloses compositions, shampoo and methods of treating dandruff with an effective amount of a particulate zinc material (such as basic zinc carbonate); 0.01-5% zinc pyrithione, 1-50% anionic surfactants. The copending application discloses cationic deposition polymers, conditioning agents, suspending agents, pH ranges, relative zinc labilities and various surfactants.

The copending application does not expressly teach the amount of zinc layered material or a ratio of surfactant to zinc layered material of greater than or equal to 2:1.

However, these are result effective variables and one of ordinary skill in the art would optimize the amount of each ingredient to arrive at the desired result.

Therefore, the Examiner concludes that one of ordinary skill in the art would have recognized the obvious variation of the instant invention over the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

**Response to arguments:**

Applicant requests that this rejection be held in abeyance until allowable subject matter is indicated. Until that time the rejection is maintained.

2. Claims 1, 3, 7-13, 18-22 and 25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 9, 13-30, 35 and 37-40 of copending Application No. 11/890684. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant subject matter embraces or are embraced by the subject matter of the copending application. The copending application discloses compositions and methods for treating dandruff comprising a particulate zinc material (basic zinc carbonate as well as every other zinc layered material instantly claimed (see claims 25 and 26)); 0.01 to about 5% zinc pyrithione; 1% to about 50% anionic surfactant; pH; relative zinc lability; cationic polymer; conditioning agent; and suspending agent.

The copending application does not expressly teach the amount of zinc layered material or a ratio of surfactant to zinc layered material of greater than or equal to 2:1 or impurity containing basic zinc carbonate.

However, these are result effective variables and one of ordinary skill in the art would optimize the amount of each ingredient to arrive at the desired result. Furthermore, the disclosure

Art Unit: 1613

of the genus of basic zinc carbonate includes all forms of basic zinc carbonate including those with impurities.

Therefore, the Examiner concludes that one of ordinary skill in the art would have recognized the obvious variation of the instant invention over the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

**Response to arguments:**

Applicant arguments are not persuasive because the copending application does teach the zinc containing layered material can be basic zinc carbonate. It is irrelevant that the instant invention does not require a conditioning homopolymer as the copending application teaches the components of the instant invention. The relative zinc lability is inherent to the basic zinc carbonate as shown by Applicant's own Declaration data in Table 1 of the Declaration and the relative zinc lability of all the sources of basic zinc carbonate is greater than the instantly claimed amounts. The rejection is maintained.

3. Claims 1, 3, 7-13, and 18-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 11-27 and 33-46 of copending Application No. 11/899106. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant subject matter embraces or are embraced by the subject matter of the copending application. The copending application discloses compositions and methods for treating dandruff, fungal and microbial infections comprising a 0.001% to about 10% zinc containing material (basic zinc carbonate); 0.01 to about

Art Unit: 1613

5% zinc pyrithione; 5% to about 50% anionic surfactant; pH is greater than about 7; relative zinc lability; cationic polymer; conditioning agent; and suspending agent.

The copending application does not expressly teach a ratio of surfactant to zinc layered material of greater than or equal to 2:1 or impurity containing basic zinc carbonate.

However, these are result effective variables and one of ordinary skill in the art would optimize the amount of each ingredient to arrive at the desired result. Furthermore, the disclosure of the genus of basic zinc carbonate includes all forms of basic zinc carbonate including those with impurities.

Therefore, the Examiner concludes that one of ordinary skill in the art would have recognized the obvious variation of the instant invention over the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

**Response to arguments:**

Applicant asserts that the copending does not teach an impurity containing basic zinc carbonate with the instantly claimed relative zinc lability as already noted by the Examiner above. This is not found to be persuasive as the copending has the same materials and the same zinc lability. The relative zinc lability is inherent to the basic zinc carbonate as shown by Applicant's own Declaration data in Table 1 of the Declaration and the relative zinc lability of all the sources of basic zinc carbonate is greater than the instantly claimed amounts. While the copending may not teach an impurity containing basic zinc carbonate, the disclosure of basic zinc carbonate embraces all forms of basic zinc carbonate including those with impurities. The

Art Unit: 1613

comprising language allows for additional components. These arguments are not persuasive and the rejection is maintained.

### ***Conclusion***

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. DERWENT-ACC-NO: 1990-217947 abstracting DE 3900243A (patent assignee Bruggemann) teaches basic zinc carbonate contains zinc oxide, zinc carbonate and basic zinc carbonate (page 2 of 3). This was the only reference to "Bruggemann basic zinc carbonate" that the Examiner could find on the patent database that disclosed the components. It is unknown if this material is the same material used by Applicant's to obtain their Declaration data as the presence of zinc oxide and zinc carbonate might explain spurious 'impurity peaks' in the XRD patterns as well as the increased 'relative zinc lability' over samples containing just basic zinc carbonate.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERNST ARNOLD whose telephone number is (571)272-8509. The examiner can normally be reached on M-F 7:15-4:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Kwon can be reached on 571-272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1613

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ernst V Arnold/  
Primary Examiner, Art Unit 1613